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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		09757688
	Filing Date		2001-01-11
	First Named Inventor	Wolfgang HEIL	
	Art Unit	1611	
	Examiner Name	CHANNAVAJJALA, LAKSHMI SARADA	
	Attorney Docket Number	PLOVIN-2A	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code†	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4196188		1980-04-01	Besins	
	2	5928668		1999-07-27	Greaves, et al.	
	3	5354563		1993-06-16	Toyotama	
	4	4913865		1986-05-22	Toyotama	
	5	5916593		1999-06-29	de Haan et al.	
	6	5585370		1996-12-17	Casper	
	7	5422119		1995-06-06	Casper	
	8	5382573		1995-01-17	Casper	

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9	5276022	1994-01-04	Casper	
10	5256421	1993-10-26	Casper	
11	5108995	1992-04-28	Casper	

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U.S. PATENT APPLICATION PUBLICATIONS

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	1	20050032756	A1	2005-02-10	Dittgen, et al.	

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FOREIGN PATENT DOCUMENTS

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	1	9827929	WO	A2	1998-07-02	SCHERING AG		<input type="checkbox"/>
	2	0115701	WO	A1	2001-03-08	SCHERING AG		<input type="checkbox"/>
	3	1214076	EP	B1	2002-06-19	SCHERING AG		<input type="checkbox"/>

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4	9804268	WO	A1	1998-02-05	AMERICAN HOME PRODUCTS CORPORATION	<input type="checkbox"/>
5	9506900	JP	T	1997-07-08	APPLIED ANALYTICAL IND INC	<input type="checkbox"/>
6	6216833	JP	A	1987-05-18	Toyotama	<input type="checkbox"/>
7	10505846	JP	T	1998-06-09	AKZO NOBEL NV	<input type="checkbox"/>
8	9501682	JP	T	1997-02-18	NOVONORDISK AS	<input type="checkbox"/>
9	9505807	WO	A1	1995-03-02	NOVONORDISK AS	<input type="checkbox"/>
10	1132523	JP	A	1989-05-25	JIKENKIYATSUPU RES LTD	<input type="checkbox"/>

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	"Summons to attend oral proceedings pursuant to Rule 115(1) EPC" dated 12 June 2008 in Opposition against EP1257280B1	<input type="checkbox"/>
	2	USP 26 The United States Pharmacopeia, (61):1791-1793 (2003).	<input type="checkbox"/>

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3	BP 2003. British Pharmacopoeia Commission. British Pharmacopoeia. London (UK): The Stationary Office; 2003: 691, 694, 707, 1037, 1235.	<input type="checkbox"/>
4	CID, E., "Cinética de Disolución de Medicamentos.". Secretaria General de la OEA. Washington, D.C., 1981. NOT AVAILABLE	<input type="checkbox"/>
5	MCGINITY JW, et al., "Bioavailability in Tablet Technology" In: Lieberman HA, Lachman L, editors. Pharmaceutical Dosage Forms: Tablets, Vol. 2. New York: Marcel Dekker Inc; 1981: 294-309.	<input type="checkbox"/>
6	WADKE, Deodatt, A. et al. "Preformulation Testing." In: Lieberman HA, Lachman L, editors. Pharmaceutical Dosage Forms: Tablets, Vol. 1 NY: Marcel Dekker; 1980: 14-16.	<input type="checkbox"/>
7	WELLS, J. "Pharmaceutical Preformulation" Ellis Horwood, 1993. NOT AVAILABLE	<input type="checkbox"/>
8	ANSEL, Introduction to Pharmaceutical Dosage Forms, 2nd Edition (1979). WHOLE BOOK. COPY NOT PROVIDED.	<input type="checkbox"/>
9	LANTZ, RUSSEL J. Jr. "Size Reduction," In: Lieberman HA, Lachman L, editors. Pharmaceutical Dosage Forms: Tablets, Vol. 2. New York: Marcel Dekker Inc; 1981: 80-81.	<input type="checkbox"/>
10	GENNARO, "Remington: The Science and Practice of Pharmacy," Mack Publishing Co., Easton, Pa., 1995:593-612.	<input type="checkbox"/>
11	JOHANSEN, H.; MOLLER, N. "Solvent deposition method for enhancement of dissolution rate: importance of drug-to-excipient ratio." J Pharm Sci. 1978 Jan;67(1):134-6.	<input type="checkbox"/>
12	MORTADA, LOBNA M., et al., "Enhancement of Dissolution Rates of Some Water Insoluble Drugs by the Solvent Deposition Technique." Acta Pharmaceutica Technologica 28(4) 1982, pp. 297-301.	<input type="checkbox"/>
13	LACHMAN, LEON and LIEBERMAN, H. "The Theory and Practice of Industrial Pharmacy." Lea & Febiger, Philadelphia, 1976: 141-161.	<input type="checkbox"/>

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14	SALOPE, E.G.; AL-SARRAJ, F.A. "Effect of Solvent-Deposition on Spironolactone Crystal Form" Drug Development and Industrial Pharmacy, 11(12), 2061-2070 (1985).	<input type="checkbox"/>
15	LAW, S.L.; CHIANG, C.H. "Improving Dissolution rates of Griseofluvin by Deposition on Disintegrants." Drug Development and Industrial Pharmacy, 16(1): 137-147 (1990).	<input type="checkbox"/>
16	MOHAMED, M. et al. "Dissolution characteristics of Ibuprofen-polyethylene glycol 6000 solid dispersions." Pharmazeutische Industrie, 47:1293-1295 (1985).	<input type="checkbox"/>
17	SINGLA, A.K.; VIJAN, T "Dissolution of Sulphamethoxazole from Polyethylene Glycols and Polyvinylpyrrolidone Solid Dispersions." Drug Development and Industrial Pharmacy, 16(5): 875-882 (1990).	<input type="checkbox"/>
18	GUPTA, R.L. et al. "Enhanced Dissolution and Absorption of Trimethoprim from Coprecipitates with Polyethylene Glycols and Polyvinylpyrrolidone." Drug Development and Industrial Pharmacy, 17(3): 463-468, 1991.	<input type="checkbox"/>
19	BOLDYREV, et al. "Preparation of the Disperse Systems of Sulfathiazole-Polyvinylpyrrolidone by Mechanical Activation." Drug Development and Industrial Pharmacy, 20(6): 1103-1114, 1994.	<input type="checkbox"/>
20	CARSTENSEN, "Pharmaceutical Principles of Solids and Solid Dosage Forms", Wiley Interscience, (1977). NOT AVAILABLE	<input type="checkbox"/>
21	BASDEVANT, et al., "Differential lipemic and hormonal responses to oral and parenteral 17 β -estradiol in postmenopausal women." Am. J. Obstet. Gynecol. 147(7): 77-81, 1983.	<input type="checkbox"/>
22	BOLAJI II, et al. "Assessment of bioavailability of oral micronized progesterone using a salivary progesterone enzymeimmunoassay." Gynecol. Endocrinol. 7(2): 101-110, 1993.	<input type="checkbox"/>
23	MURRAY, J.L. "Natural Progesterone: What Role in Women's Health Care?" Women's Health in Primary Care, 1 (8):671-687, 1998.	<input type="checkbox"/>
24	"The United States Pharmacopeia, The National Formulary", USP 23 NF 18 (1995), pp. 1791-1793.	<input type="checkbox"/>

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25	BUDAVARI, et al. "The Merck Index." Merck & Co., Inc., Whitehouse Station, NJ. 2001: 3489.	<input type="checkbox"/>
26	VAN WINTER JT, BERNARD ME. "Oral Contraceptive Use During the Perimenopausal Years." Am Fam Physician 1998;58:1373-80.	<input type="checkbox"/>
27	American Society for Reproductive Medicine, "New Progestins in Women's Health." Medical Association Communications 1999-2003.	<input type="checkbox"/>
28	WETZEL, W. "Micronized progesterone: A new option for women's health care." The Nurse Practitioner. 1999; 24:62-76.	<input type="checkbox"/>
29	APGAR, B. "Using Progestins in Clinical Practice." American Family Physician. 2000 Oct 15;62(8):1839-1846, 1849-1850.	<input type="checkbox"/>
30	NICKISCH et al., "Acid-Catalyzed Rearrangements of 15(3, 16(3-methylene-17a-pregnene-21,17- carbolactone Derivatives," Tetrahedron Letters, vol. 27, No. 45, 1986, pp. 5463-5466.	<input type="checkbox"/>
31	ROWE et al. Handbook of Pharmaceutical Excipients. 4th ed. Washington (DC): American Pharmaceutical Association, 2003: 108-111, 432-437.	<input type="checkbox"/>
32	GENNARO et al. Remington's Pharmaceutical Sciences. 18th Edition. Mack Publishing Co., Easton, PA, 1990: 589-602.	<input type="checkbox"/>
33	KRISTENSEN, Henning G. Almen farmaci, Institut for Farmaci, Danmarks Farmaceutiske Højskole, 3. udgave (2000).	<input type="checkbox"/>
34	Reference No. D26 cited on 2008-12-06 in EPO Opposition to EP01900579.2.	<input type="checkbox"/>
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36	Reference No. D19 cited on 2008-12-06 in EPO Opposition to EP01900579.2.	<input type="checkbox"/>
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EXAMINER SIGNATURE

Examiner Signature	/Lakshmi Channavajjala/	Date Considered	05/27/2009
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